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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/003,740	10/31/2001	Mel Epstein	NIIN-P01-011	2709

21005 7590 08/13/2003

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EXAMINER	
KWON, BRIAN YONG S	

ART UNIT	PAPER NUMBER
1614	14

DATE MAILED: 08/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/003,740	Applicant(s) EPSTEIN ET AL.	
	Examiner Brian S Kwon	Art Unit 1614	

-- The MAILING DATE f this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 April 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *91-119* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *91-119* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *5,6,11* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Applicants Response to Restriction Requirement

1. Applicants election with the Group II(a), claims 24-47 and 55-78, directed to a method of treating memory impairment with amphetamine and the species l-amphetamine, is acknowledged.

2. By Amendment filed on April 2, 2003, claims 1-90 have been cancelled and claims 91-119 have been newly added. It appears that new claims 91-119 are similar to the elected Group II(a) and are commensurate in scope with the invention of the elected Group II(a). Therefore, claims 91-119 will be included in Group II(a) and examined for prosecution on the merits.

Priority

3. Applicant's claim for domestic priority benefit of 60/245,323 filed 11/01/2000 under 35 U.S.C. 119(e) is acknowledged.

Information Disclosure Statement

4. Enclosed is an initialed copy of PTO 1449 which has been considered for your records, Application No. 10/003740.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 91-119 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gelowits et al. (Pharamcology biochemistry and Behavior, Vol. 47, pp. 41-45, 1994) in view of Soetens et al. (Neurosciene Letters, 161, 1993, 9-12) and if necessary, further in view of Brown et al. (Behavioural Brain Research 114, 2000, 135-143).

Gelowitz teaches or suggests the use of L-amphetamine in improving cognitive function, namely learning and spatial working memory (abstract; page 42, column 1, para. 1; page 44, column 2, para. 1). Gelowitz also teaches or suggests that D-amphetamine is known to be more active form than its levo-form and the use of D-amphetamine is associated with the adverse

effects such as the development of tolerance and physical dependence but not to L-amphetamine (page 43, column 2, para. 4 thru page 44, column 1, para. 1).

Soetens teaches or suggests the use of amphetamine, namely D-amphetamine in enhancing memory consolidation (abstract; page 11, column 1, para. 2 and column 2, para. 1).

The teaching of Gelowitz differs from the claimed invention in (i) the use of L-amphetamine in enhancing memory consolidation or long-term memory in the specific mole percent l-amphetamine, namely "at least about 90 mole percent l-amphetamine" or "at least about 99 mole percent l-amphetamine"; (ii) the specific dosage amount of administered l-amphetamine in "single dose" or "multiple dose"; and (iii) the use of assessment tool to evaluate the degree of impairment in memory prior to the l-amphetamine treatment and the degree of improvement in memory consolidation after the treatment.

To incorporate such teaching into the teaching of Gelowitz, would have been obvious in view of Soetens who teaches or suggests the use of amphetamine, namely D-amphetamine in enhancing memory consolidation. One having ordinary skill in the art would have known that amphetamine in either L-amphetamine or D-amphetamine is useful in improving learning and working memory. Further, one having ordinary skill in the art would have expected that l-amphetamine would have memory-consolidation-enhancing activity as D-amphetamine. Therefore, one having ordinary skill in the art would have been motivated to administer amphetamine, a known compound to have memory-consolidation-enhancing activity, in the form of l-amphetamine or essentially l-amphetamine to enhance memory consolidation or long-term memory in patients at risk of having or having tolerance development or physical dependence.

One having ordinary skill in the art would have been motivated to do such that the adverse effects associated with D-amphetamine would be greatly reduced.

In addition, those of ordinary skill in the art will readily optimize effective dosages and concurrent administration regimens as determined by good medical practice and the clinical condition of the individual patient. Regardless of the manner of administration, the specific dose may be calculated according to body weight, body surface area or organ size. Further refinement of the calculations necessary to determine the appropriate dosage for treatment involving each of the above mentioned formulations is routinely made by those of ordinary skill in the art and is within the ability of tasks routinely performed by them without undue experimentation. Furthermore, the assessment of degree of impairment in memory consolidation before the treatment and the determination of improvement in memory consolidation post to the treatment is well considered within the skill of the artisan since the assessment of patients condition and monitoring of the treatment outcome is routinely done in the clinical setting. Appropriate treatment regimen will be determined by the attending physician, considering the severity of patient's condition (impairment), the responsiveness of the subject, the age and other clinical factors.

Conclusion

7. No Claim is allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Kwon whose telephone number is (703) 308-5377. The examiner can normally be reached Tuesday through Friday from 9:00 am to 7:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached on (703) 308-4725. The fax number for this Group is (703) 308-4556.

Any inquiry of a general nature of relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

Brian Kwon

ZOHREH FAY
PRIMARY EXAMINER
GROUP 1600